



**Virginia  
Regulatory  
Town Hall**

## Proposed Regulation Agency Background Document

<b>Agency Name:</b>	Department of Mental Health, Mental Retardation and Substance
<b>VAC Chapter Number:</b>	12 VAC 35-102-10 et seq. and 12 VAC 35-105 et seq.
<b>Regulation Title:</b>	Rules and Regulations for the Licensing of Providers of Mental Health, Mental Retardation and Substance Abuse Services
<b>Action Title:</b>	Repeal Regulations 12 VAC 35-102-10 et seq. and promulgate Replacement Regulations 12 VAC 35-105 et seq.
<b>Date:</b>	June 4, 2001

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

### Summary

*Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

These regulations provide standards for licensing of providers by the Department of Mental Health, Mental Retardation and Substance Abuse Services (Department). The regulations include specific standards governing administration, clinical services, support functions and physical environment of a licensed provider that are designed to protect the health, safety and welfare of individuals receiving services from such providers. The regulations also identify the services for which a provider may be licensed and describe the process for obtaining a license from the Department. In addition, the regulations outline the procedures to be used by the Department to monitor providers' compliance with the specific requirements for licensing,

describe the basis for revocation or refusing to issue a license, and the circumstances under which a provisional license or sanctions may be issued.

### Basis

*Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.*

There are several Virginia Code sections that authorize the promulgation of these regulations. Section 37.1-179.1 of the Code of Virginia grants permissive authority to the Mental Health, Mental Retardation and Substance Abuse Services Board (Board) to promulgate regulations authorizing the Commissioner to issue licenses to “any suitable provider to establish, maintain and operate, or to have charge of any service for persons with mental illness, mental retardation or substance addiction or abuse.” In addition, Section 37.1-182 of the Code of Virginia indicates that “all services provided or delivered under any such license shall be subject to review or inspection at any reasonable time by any authorized inspector or agent of the Department” and grants the Board permissive authority to promulgate regulations to carry out such inspections.

There are also several sections of the Code that mandate promulgation of regulations that pertain to the licensing of mental health, mental retardation and substance abuse services and providers. Section 37.1-182.1 of the Code of Virginia requires adoption of regulations to “ensure that providers licensed to offer substance abuse treatment develop policies and procedures which provide for the timely and appropriate treatment for pregnant substance abusing women.” Section 37.1-185.1 of the Code of Virginia requires the Board to promulgate regulations for imposing civil penalties on licensed providers that violate certain legislative mandates regarding human rights and licensing requirements. Violations of these regulations can result in the imposition of civil penalties. Section 37.1-188.1 of the Code of Virginia requires the Board to promulgate regulations to govern advertising practices of any license provider to ensure that advertisements are not false or misleading.

Section 37.1-219 of the Code also requires the Board to “...adopt reasonable regulations prescribing standards for substance abuse treatment programs to ensure proper attention, service and treatment to persons treated in such programs.” Section 37.1-221 requires the Board to “...adopt regulations for acceptance of persons into approved substance abuse treatment programs.”

The Office of the Attorney General has certified that the proposed regulations are “...consistent with statutory authority, do not conflict with existing law and appear to be constitutional.”

## Purpose

*Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.*

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The Department of Mental Health, Mental Retardation and Substance Abuse Services is proposing to replace the current licensing regulations for the following reasons:

- To reorganize and clarify the regulations consistent with current practice and terminology;
- To include the process for licensing in the text of the regulations, including provisions for variances and sanctions. Such provisions are not included in current regulations;
- To provide greater specificity in the providers' responsibilities, especially for qualifications of employees and supervisors, requirements for assessments and service planning, and requirements for responding to the medical needs of individuals receiving services;
- To incorporate the recent changes in licensing laws, including requirements for staff background checks;
- To ensure that provisions for licensing comply with the Board's regulations for human rights. Recent changes to the law require compliance with human rights regulations as a prerequisite for licensing providers; and
- To incorporate provisions for licensing additional services (i.e. case management, community gero-psychiatric residential services) consistent with amendments to the law that were enacted in 2001.

These changes and updates are necessary to conform the regulations to recent changes in the law; to ensure the protection of individuals receiving services; to increase the accountability of providers and to provide greater flexibility in tailoring programs and services to meet individual needs.

With the proposed changes and updates, the regulations will provide the basis for the Department to issue licenses, as required by § 37.1-183.1, to persons who establish services "...for the care or treatment of mentally ill or mentally retarded persons, or persons addicted to the intemperate use of narcotic drugs, alcohol or other stimulants..."

## Substance

*Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.*

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The proposed regulations include new sections that explain the authority and applicability of the regulations and the licensing process that are not included in the current regulations. Specific

requirements for sponsored residential home services, case management services, community gero-psychiatric residential services and intensive community treatment and programs of assertive community treatment services have also been included in the proposed regulations.

The regulations require all residential and inpatient locations to be in compliance with specific residential physical environment requirements. The current practice of the Office of Licensing is to apply these regulations through a separate facility license that applies only to residential locations with five or more beds. Under the new proposed regulations, the Department will not issue separate facility licenses but will specify the number of licensed beds on the license addendum and regularly review compliance of all residential locations, regardless of the number of beds, with the residential physical environment requirements.

New definitions have been added including, “corrective action plan,” “crisis,” “individual,” “medication error,” “neglect,” “provider,” “restriction,” and “serious injury.” and many definitions have been updated and revised. Documentation requirements are added and policies are required to be implemented.

The regulations have been reorganized, especially Part III “Services and Supports,” and provisions have been strengthened. Supervision requirements have been added to the provider staffing plan. The admission process must include a preliminary assessment to determine eligibility for services and to develop a preliminary individualized services plan. The preliminary individualized services plan must be developed and implemented within 24 hours of admission and the complete individualized services plan must be developed and implemented within 30 days. Health care policy regulations are also strengthened.

## Issues

*Please provide a statement identifying the issues associated with the proposed regulatory action. The term “issues” means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.*

The new regulations will build on the current regulations by clarifying and reorganizing the requirements. This should facilitate compliance by reducing ambiguity and providing more detailed guidance to providers regarding the specific requirements. This clarification should also improve the agency’s ability to monitor the provider’s compliance with the standards.

The revisions should also provide greater protection for individuals receiving services and their families in response to individual needs. The agency has generally found that individuals receiving services in licensed programs have more complex disabilities and needs than those that have been served in the past. The proposed amendments are needed to effectively safeguard this population. The new regulations strengthen the requirements in areas such as physical environment, staff supervision, and individualized service planning.

There are no disadvantages to the public or the Commonwealth associated with the promulgation of the proposed regulations.

### Fiscal Impact

*Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.*

There are no projected new or additional costs for the agency to implement the revised regulations beyond the ongoing expenditures for the Office of Licensing. The current workload should not be significantly affected by the addition of new licensed categories of services under the proposed regulations, specifically community gero-psychiatric residential services and case management services. The Department anticipates few, if any, providers will seek licenses to provide community gero-psychiatric residential in the near future because this type of service has not been fully developed in the professional or provider community and it is not reimbursed by Medicaid (or other third party payers).

It is projected that all 40 Community Service Boards/Behavioral Health Authorities will need to be licensed as case management providers within the six months following the effective date of these regulations. The Office of Licensing expects that many of these licenses can be issued as part of the current planned workload of the Office of Licensing. Sufficient data is not available to project the number of potential private case management service providers. Initially, the Office of Licensing projects that existing staff will be able to absorb the additional licensing workload.

The regulations could potentially have a financial impact on some providers who will be required to comply with new physical environment requirements for service locations and requirements for staff qualifications under these regulations. However, any impact should be minimal because it is expected that the affected providers already meet most of the new standards that are incorporated into the proposed regulations.

The budget of the Office of Licensing is a part of the Administration and Support activity of the DMHMRSAS. The total allocated to the office for the current fiscal year is \$1,118,806.

These regulations will affect approximately 350 licensed providers offering more than 1,000 licensed services at more than 2,000 locations around the Commonwealth.

### Detail of Changes

*Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This*

*statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.*

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The following discussion details changes to the existing licensing regulations (12 VAC 35-102-10 et seq.) that have been incorporated into the proposed replacement regulations.

The “Introduction” (Part I) of the proposed regulations includes general provisions in Article I (“Authority and Applicability”) and Article 3 (“Licensing Process”) that are not addressed in the existing regulations. Article 2 (“Definitions”) provides definitions of various services and other key words used in the regulation. New services and terms such as, “corrective action plan,” “crisis,” “individual,” “medication error,” “neglect,” “provider,” “restriction,” and “serious injury,” have been defined in the proposed regulations that are not included in the current regulations and many definitions have been updated and revised. Definitions have also been revised to be consistent with other agency regulations (e.g. Human Rights Regulations).

Parts II-IV of the regulations are requirements that apply to all service providers. Any exemptions or specific applicability are detailed in these sections of the regulations.

Part II is titled “Administrative Services.” The substantive changes from the current regulations include:

- Requirements for compliance with § 37.1-197.1 of the Code of Virginia regarding prescreening and predischarge planning;
- Required timeframes for submitting corrective action plans;
- Requirements for annual operating statements and balance sheets;
- More specific requirements for general physical environment, including room temperatures, hot water temperatures, floor surfaces, and lighting;
- A 20 bed limit for new community intermediate care facilities for individuals with mental retardation (ICF/MR). Existing community ICF/MRs would be grandfathered;
- A requirement for providers of services to give individuals a partial bath, clean clothing, and linens each time their clothing or bed linen is soiled;
- Provisions to comply with Code requirements for providers to submit criminal background checks and search the registry of founded complaints of child abuse and neglect maintained by the Department of Social Services;
- Clarification that program directors must have experience in working with the population served and in providing the services outlined in the service description;
- Clarification that the knowledge, skills, and abilities, professional qualifications, and experience required for each job description be appropriate to the duties and responsibilities required of the position;
- A requirement that orientation of new employees must be completed within 14 calendar days;
- Retraining requirements;
- Prohibition on a provider’s reliance on students and volunteers for the provision of direct care services;

- Requirements to develop a prevention/management program for populations identified at risk for falls; and
- More detailed requirements for an emergency preparedness and response plan.

Part III of the proposed regulations is titled “Services and Supports.” The “Service Description” and “Staffing” sections were relocated from the “Administrative Services” section from the current regulations. “Medical Management,” “Medication Management” and “Behavior Management” sections were moved from the “Specialized Services” in the current regulations. This relocation is intended to indicate that medical management, medication management, and behavior management are considered basic services. Substantive new provisions include:

- A requirement that providers document that each service offers a structured program of care designed to meet the individuals’ physical and emotional needs;
- A requirement for the physical separation of children and adults in residential and inpatient services and separate group programming for adults and children;
- A requirement that supervisors for mental health or mental retardation services be a “Qualified Mental Health Professional” or “Qualified Mental Retardation Professional,” as defined in the regulations, or an individual with equivalent experience;
- A requirement that providers employ or contract with persons with appropriate training as necessary to serve the needs of individuals with medical or nursing needs, speech or hearing problems, or other needs where specialized training is necessary;
- Requirements for preliminary assessments to determine whether the individual qualifies for admission;
- A requirement that providers develop and implement a preliminary individualized services plan within 24 hours of admission and a complete individualized services plan within 30 days. The plan is to be reviewed and revised quarterly and rewritten annually;
- A requirement that individualized services plans address any medical care needs appropriate to the scope and level of service either by providing medical care, arranging for medical care or referring for medical care; and
- A requirement that residential service providers either administer or obtain results of physical exams within 30 days of admission.

A new Part IV has been created that pertains exclusively to “Records Management.” This part consists of provisions compiled from other parts of the current regulations, although there are no substantive changes in Part IV.

Part V is titled “Additional Requirements for Selected Services.” Part V in the proposed regulations replaces the section titled “Specialized Services” in the existing regulations and has been renamed to more accurately reflect the content. Providers of these “selected services” must comply with the requirements for all providers in Parts II-IV of the proposed regulations as well as the additional requirements in Part V. The first three articles “Opioid Treatment Services,” “Sobering up and Detoxification Services,” and “Services in Correctional Facilities,” are revised from the current regulations. In particular, “Opioid Treatment Services” was revised to be consistent with new federal regulations.

Part V also includes additional new requirements for licensing for sponsored residential home services, case management services, community gero-psychiatric residential services, and intensive community treatment and program of assertive community treatment services.

There are currently no specific provisions for licensing sponsored residential home services under the current regulations. Licenses are currently issued for sponsored residential home services under existing regulatory provisions for sponsored placement services. The proposed regulations include specific provisions for licensing sponsored residential home services which will result in greater accountability from providers of sponsored placement services with regard to physical environment, selection and training of the sponsors and the provision of services. The provider is also responsible for providing basic information on the sponsored residential homes to the Department and maintaining written agreements with the sponsors. The maximum number of beds for individuals receiving services in a sponsored residential home is two.

An amendment to the Code of Virginia that was enacted during 2001, authorizes the Department to license case management services and community gero-psychiatric residential services. The proposed regulations outline requirements for licensing case management services and the qualifications for case managers. New provisions have also been included for licensing community gero-psychiatric residential services in this section.

The existing regulations do not include specific provisions for licensing intensive community treatment and programs of assertive community treatment services. Such services are now licensed under existing general criteria. The new regulations include criteria for admission, treatment team and staffing plan, contacts, daily operation and progress notes, assessments and services which are intended to address the prescriptive nature of this intensive service model.

## Alternatives

*Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.*

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Several Alternatives have been considered in developing these regulations.

Alternative 1 – No regulations. Repealing the licensing regulations without replacing them would eliminate an important tool for protecting the health and safety of individuals receiving services. The Department has opted to use the authority granted by section 37.1-179.1, et seq. of the Code of Virginia to license such providers.

Alternative 2 – No change to the Licensing Regulations. The current regulations were effective January 13, 1995 and are now outdated. The Department, providers and advocates have identified a number of changes that will improve the process of licensing of providers and increase the protection of individuals receiving services. Individuals receiving services in licensed programs generally have more complex disabilities and needs than those served when the regulations were developed. Revised regulations are needed to effectively safeguard this population. In addition, statutory changes in 2001 require changes in the regulations.

Alternative 3 – Amend the regulations. The number of additions and changes as well as the recommended reorganization makes it difficult to revise the current regulations.

Alternative 4 – Repeal the current licensing regulations and promulgate new regulations. The number of additions and changes as well as the recommended reorganization makes it desirable to replace the current licensing regulations with new licensing regulations rather than amend the current regulations.

## Public Comment

*Please summarize all public comment received during the NOIRA comment period and provide the agency response.*

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The Department contacted more than 400 interested persons and organizations, including all licensed providers, regarding the publication of the Notice of Intended Regulatory Action (NOIRA) in the Virginia Register on February 12, 2001, which requested public comment for 30 days following publication. Two responses were received. The Department also worked with an internal work group of disability and program specialists within the Department and with an external work group of public and private providers, advocacy organizations, related state agencies and interested persons to seek technical assistance in the preparation of the proposed regulations. An exposure draft was distributed to the external work group and the Department held two meetings of the external work group to review the exposure draft. Many of the comments are incorporated in the proposed regulation.

The following is a summary of the specific public comments that were received in response to the NOIRA and the agency response.

1. The Virginia Alliance of Methadone Advocates: This organization requested that the Department (a) not add any unnecessary restrictive rules to the new federal regulations covering opioid treatment services; (b) change terminology from client to patient; (c) change terminology from opioid replacement treatment to opioid agonist treatment; (d) accept and encourage clinics to allow 14 and 30 day take home medication for stable patients; (e) allow for the dispensing of dry take home medication to stable patients; (f) allow for and actively pursue "...Office Based Methadone Treatment for stable patients using the Hub Model..." (a theoretical model for patient treatment); and (g) include patients in the accreditation process that will be required by the new regulation.

### Agency Response:

The Department did not add any rules beyond the recently revised federal requirements. These regulations are consistent with the human rights regulations adopted by the Board, which uses the term "individual receiving services" to mean any persons receiving care or treatment or other services from a provider licensed under these regulations. Therefore, the Department has not changed the terminology, as suggested. The regulations use the term opioid treatment services because the recently revised federal regulations use similar terminology. The proposed

definition makes it clear that this service involves opioid agonist treatment medication. The regulations are silent about the length of time medication can be dispensed for take homes and the dispensing of dry take home medication to stable patients. Federal regulations governing this aspect of treatment are considered to be adequate. The proposed regulations would not prevent providers from offering services according to the “hub model.” The state has no role in the accreditation process. The accreditation process is part of federal regulations.

2. Parents and Associates of the Institutionalized Retarded (PAIR): This organization re-submitted the same written comments that it had previously submitted as part of the periodic review process. Many of the comments concerned the role of the legal guardian/authorized representative in receiving notification, participating in service planning and providing consent to treatment for an individual receiving services in licensed service programs. This respondent was concerned that some of the definitions and terms used in the existing regulations for licensing did not correspond to the definitions that are part of the regulations for human rights, which are currently in the final stages of promulgation. PAIR also recommended: (a) requiring immediate corrective action when a violation poses a danger to clients; (b) specifying acceptable room temperatures of 68 to 85 degrees; (c) prohibitions on the reliance on students or volunteers for the provision of direct services and (d) requiring adequate staffing and planning for emergencies.

Agency Response: The Department has incorporated many of PAIR’s suggestions into the proposed regulations. The definitions and general requirements concerning the legally authorized representative were developed specifically to correspond to the regulations for human rights and applicable Virginia Code requirements. The proposed regulations require immediate corrective action when a violation poses a danger to individuals receiving services and a temperature range of 65 to 80 degrees. The Department agrees that providers should not rely on students or volunteers for the provision of direct services and has included provisions to address this issue in the proposed regulations. The Department revised and expanded the requirements for the emergency preparedness and response plan in the proposed regulations.

The Department is likely to receive comments in many of the subject areas addressed by PAIR during the public comment period on the proposed regulations. These issues will be reconsidered, if necessary, in light of any additional comments received on the proposed regulations.

### Clarity of the Regulation

*Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.*

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The Department of Mental Health, Mental Retardation and Substance Abuse Services has reviewed the regulations, held workgroups with providers, licensing specialists, advocates, and consumer and family representatives, and incorporated comments from earlier drafts to ensure that the regulation is clearly written and easily understandable. In addition, the Department has

brought in expert consultants to assist in the development of specific components and to review the proposed regulations.

### Periodic Review

*Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.*

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The Department of Mental Health, Mental Retardation and Substance Abuse Services will review and evaluate the need for amendments or revision to this regulation no later than three years following the effective date of the new regulations and every three years thereafter.

### Family Impact Statement

*Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

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This regulation describes the minimum standards that providers of mental health, mental retardation and substance abuse services must meet in delivering services. The minimum standards are designed to protect the health, safety and welfare of individuals receiving services. Such assurance provides peace of mind to many families who have entrusted the care and well-being of their children, parents, brothers, sisters, or other relatives to a service provider.

The regulation does not erode the authority and rights of parents in the education, nurturing and supervision of their children. The regulations require providers to comply with the human rights regulations in regards to participation in individual decision making by the individual or legally authorized representative. The human rights regulations require providers to obtain the consent of at least one parent of a minor before treatment, including medical treatment, begins. It outlines the provisions for an individual's next of kin to be designated as a legally authorized representative when an individual lacks the capacity to give consent for any treatment. The licensing regulations also require providers to involve family members in developing or revising the individualized services plan consistent with laws protecting confidentiality, privacy, the human rights of individuals receiving services and the rights of minors.

This regulation does not discourage the economic self-sufficiency, self-pride and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents. Providers are required to develop and implement individualized services plan that address the relevant psychological, behavioral, medical, rehabilitation and nursing needs as indicated by a complete assessment and that address the individual's needs and preferences.

This regulation has no effect on the marital commitment or on family income.